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| 10/748,625 | 12/27/2003 | Kishore R. Shah | KS4 | 7504 |

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| EXAMINER |
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ROGERS, JAMES WILLIAM

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| ART UNIT | PAPER NUMBER |
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1618

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03/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/748,625

Applicant(s)

SHAH, KISHORE R.

Examiner

JAMES W. ROGERS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6, 8-10, 12-16 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) 9, 12-15, 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 8, 10, 16, 18 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/24/2008 has been entered.

Applicants amendments to the claims have been entered. Applicants have amended claims 1,16 and 21. Any rejection from the previous office action filed 11/30/2007 not addressed below has been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3,6,8-10,16,18-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1,16 and 21 recite that the carrier is a hydrophilic water based carrier selected from the group consisting of a

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solution, emulsion, dispersion, lotion, cream, petrolatum and a wax-based preparation, there is insufficient disclosure within the specification for this limitation. The above Markush group is taken directly from the specification on page 4 lines 24-27 that describes the final dosage form of the hydrophilic polymer film forming composition. The only description within the specification for the types of carriers is hydrophilic or hydrophobic carriers.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,16 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1,16 and 21 all recite a hydrophilic water based carrier selected from the group consisting of a solution, emulsion, dispersion, lotion, cream, petrolatum and a wax-based preparation, the Markush group is limiting to the type of formulation not the carrier which should be a material substance ie water, organic solvents etc., therefore the limitation is indefinite.

Response to Arguments

Applicant's arguments filed 01/24/2008 have been fully considered but are not persuasive.

Applicants assert that carrier as applied to skincare or dermatological products refers to a **composition** in which an active ingredient is incorporated to produce a

suitable product formulation. Thus applicants surmise the term carrier is not restricted to solvents only but encompasses their claimed Markush group. Applicants further assert the term carrier is a means for uniformly applying the graft copolymers to the skin in the form of a film. Applicants state the preparation of the dosage forms in the specified carriers for skin treatment are described at [0024].

The relevance of these assertions is unclear. Paragraph [0024] describes **dosage forms** for topical application, the Markush group applicants claim is not defined as carriers but rather as dosage forms. Thus applicant's specification describes the Markush group within the claims as dosage forms not carriers which means the claims do not have written description and they are indefinite. As further evidence that that carriers are known in the art to be distinct compounds Nelson (US 5,360,788) teaches personal care compositions including skin care medicaments and describes carriers as water, petroleum jelly, mineral oil, lanolin, aloe and fatty acids. The examiner understands that applicants can be their own lexicographers, however applicants did not define the Markush group claimed as carrier but rather as dosage forms, therefore applicants have not described the above dosage forms as being carriers. See abstract and col 2 lin 50-53. It is suggested by the examiner that the limitation is deleted from the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior

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art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1-3,6,8,10,16,18 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrissey et al. (US 6,106,820).

Morrissey discloses cosmetic formulations for use as facial moisturizers, lipsticks and mascaras comprised of 0.1-50% based on weight of the composition of a graft copolymer that contained A) 50 to 98% of the copolymer comprised a backbone that included acrylic acid and methacrylic acid, B) 2% to about 50% of a hydrophilic side chain or optionally one or more types of hydrophobic monomers that could be comprised of styrene, 50-99.9% of a carrier including water, 0.1-10% of thickeners selected from hydroxyethyl cellulose, hydroxypropyl cellulose and xanthan gum and therapeutic agents such as anti-microbials and vitamins. See abstract, col 4 lin 4-47, col 6 lin 16-52, col 12 lin 11-42, col 13 lin 47-67, col 17 lin 33-56 and examples 4-5 and 10-13. The above ranges for the ingredients and copolymer components overlap applicants claimed range, therefore applicants claimed range would have been obvious

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to one of skill in the art because optimizing the amounts of ingredients within a topical composition is considered routine and ordinary practice. A prima facie case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art. E.g., In re Geusler, 116 F.3d 1465, 1469, 43 USPQ2d 1362, 1365 (Fed. Cir. 1997); In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936-37 (CCPA 1976); In re Malagari, 449 F.2d 1297, 1202, 182 USPQ 549, 553 (CCPA 1974). It is the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) ("[D]iscovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art." See, e.g., In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In re Paterson Appeal No. 02-1189 (Fed. Cir. January 8, 2003). Morrissey discloses that the graft copolymers can be in a single phase or multiple phase and dispersed within the diluent (water), thus meeting applicant's limitation of a homogeneous dispersion. Morrissey also discloses that the compositions can be formulated into several forms including creams, lotions and gels which could be used for a number of cosmetic purposes including foundations, lipstick, mascaras, eyeliner, wrinkle reducing creams and the like. See col 13 lin 47-col 14 lin 48. Morrissey also discloses that a standard brush-applicator can be used to apply the disclosed compositions, thus meeting the limitation within claim 10. See col 18 lin 55-col 19 lin 7. Regarding claim 21 the examiner notes that the claim is drawn to a

method of treating a mammalian skin with a bio-adhesive, film forming composition, thus the steps of forming the composition (parts a and b) are essentially product by process limitations. Since the composition described by Morrissey is essentially the same as applicants the claim limitations are met because, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Response to Arguments

Applicant's arguments filed 01/24/2008 have been fully considered but are not persuasive.

Applicants assert that Morrissey does not teach a polymer with a hydrophilic backbone and a hydrophobic polystyrene side chain as in their currently amended claims. Instead applicants assert Morrissey discloses exactly the opposite type of graft copolymers in which applicants are claiming because Morrissey states the side chains are hydrophilic and must be present. Furthermore applicants assert that it would be apparent to those skilled in the art that the backbone would have to be hydrophobic to be able to retain the hardness, rigidity and toughness required.

The relevance of this assertion is unclear. Morrissey clearly teaches that the backbone can be derived from hydrophilic monomers, hydrophobic monomers or mixtures thereof, some of the preferred monomers that can comprise the backbone includes acrylic acid, dimethylacrylamide, methacrylic acid and mixtures thereof. The examiner notes that all of the examples in applicant's specification included acrylic acid and dimethylacrylamide as part of the main chain. Also Morrissey clearly states that the side chains can be derived from hydrophilic monomers and hydrophobic monomers and goes so far as to list styrene as being a preferred monomer. See col 4 lin 7-col 6 lin 52. Applicants transitional phrase "comprising", which is synonymous with "including", "containing", or "characterized by", is inclusive or open ended and does not exclude additional elements or method steps recited in the prior art. *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003). Thus even though Morrissey does disclose the use of hydrophilic monomers for the graft chains these chains are not excluded by applicants transitional phrase "comprising".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3,6,8,10,16,18 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah (US. 5,942,243, cited by applicant) in view of Morrissey et al.

(US 6,106,820), a new reasoning for a rejection over the references above were necessitated by applicants amendment and a new rejection of new claims 21-24 was necessitated by amendment.

Shah is disclosed previously in the office action dated 09/21/2006, 01/26/2007 and 07/09/2007. Shah discloses the exact same copolymer as within applicants claims. Shah is silent on if the copolymers disclosed within would form a homogenous dispersion in a water-based carrier. Shah also does not disclose the use of the composition as a face make up and the specific applicator for applying the topical composition.

Morrissey is disclosed above. Morrissey is used to primarily show that graft copolymers were well known to be capable of being dispersible within a liquid diluent such as water. See col 12 lin 5-33. Morrissey also discloses that the compositions can be formulated into several forms including creams, lotions and gels which could be used for a number of cosmetic purposes including foundations, lipstick, mascaras, eyeliner, wrinkle reducing creams and the like. See col 13 lin 47-col 14 lin 48. Morrissey also discloses that a standard brush-applicator can be used to apply the disclosed compositions. See col 18 lin 55-col 19 lin 7.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Shah discloses the same copolymers as applicants claimed invention but is silent on if it forms a homogeneous dispersion with water while Morrissey discloses that it was already well known and understood in the art that compositions comprised of

graft copolymers within the scope of applicant's claimed invention could form homogeneous dispersions with water. Morrissey also discloses that compositions containing such copolymers could be used for facial compositions and applying by spray and brush. Thus the claimed invention would have been *prima facie* obvious since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Response to Arguments

Applicant's arguments filed 05/30/2007 have been fully considered but they are not persuasive.

Applicants assert that formation of homogeneous stable dispersion in water is not obvious from '243. Applicants assert that as shown during the previous interview that exemplary hydrogels (Tecogel) did not produce a homogenous dispersion, thus applicants surmise it would not be obvious to expect that the graft copolymers of '243 would produce homogeneous and stable dispersions in water. Applicants assert the claimed composition actually has two phases a dispersed copolymer particulate and the continuous aqueous phase and this feature further differentiates their invention from either '243 or Morrissey.

The relevance of these assertions is unclear. Clearly Morrissey describes that the graft copolymers are soluble or dispersible in at least one liquid diluent, the entire system can be a single phase system or a multiple phase system. Regarding applicants

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assertion that the homogeneous dispersion is a two phase system, firstly this is not a limitation within the claims and secondly a dispersion is simply a system of fine particles, evenly distributed in a medium, thus the examiner interpreted the limitation as such. The fact that a dispersion is a system of fine particles inherently means that the system comprises two phases (solid particles and liquid). Since Morressey discloses dispersions of the copolymer in liquid diluents the combination of references as detailed above renders applicant's claimed invention obvious.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618